



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,657	04/18/2005	Karina Drumm	129402.00201	9864
7590 Raymond A Miller Firm 21269 One Mellon Center 50th Floor 500 Grant Street Pittsburgh, PA 15219				
EXAMINER				
WOLLENBERGER, LOUIS V				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
04/04/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/511,657

**Applicant(s)**

DRUMM ET AL.

**Examiner**

Louis Wollenberger

**Art Unit**

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-6, 9, 10, 16, 19 and 94-98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 4-6, 9, 10, 16, 19, and 94-98 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 2/7/08 to the Notice of Non-Compliant Amendment mailed 1/24/08 is acknowledged. Also acknowledged are Applicant's amendments to the claims.

While the claims are acceptable in their current form, Applicant is notified that pursuant to 37 CFR 1.121(c)(4)(i), "No claim text shall be presented for any claim in the claim listing with the status of "canceled." In the instant case, Applicant has included the text of cancelled claims 92 and 93. Applicant is respectfully requested to cancel the text in response to this communication.

With entry of the amendment filed 2/7/08, claims 1, 4-6, 9, 10, 16, 19, and 94-98 are pending and subject to restriction as follows.

### ***Election/Restrictions***

Applicant's amendments to the claims, adding new claims 94-98, necessitates the following further restriction.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 4-6, 9, 10, 16, 19, 94, and 98, drawn to a method for the treatment of an eye disorder comprising administering a therapeutically effective amount of a dsRNA and preparing said dsRNA.

Art Unit: 1635

Group II, claim(s) 4-6, 9, 10, 16, 19, 95, and 98, drawn to a method for the treatment of an eye disorder comprising administering a therapeutically effective amount of a dsRNA and diagnosing a subject with a disorder of the eye.

Group III, claim(s) 4-6, 9, 10, 16, 19, 95, and 98, drawn to a method for the treatment of an eye disorder comprising administering a therapeutically effective amount of a dsRNA and diagnosing a subject with a predisposition to a disorder of the eye.

Group IV, claim(s) 4-6, 9, 10, 16, 19, 96, and 98, drawn to a method for the treatment of an eye disorder comprising administering a therapeutically effective amount of a dsRNA and detecting a product of the target gene of said dsRNA.

Group V, claim(s) 4-6, 9, 10, 16, 19, 97, and 98, drawn to a method for the treatment of an eye disorder comprising administering a therapeutically effective amount of a dsRNA and isolating the target gene of said dsRNA.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Groups I-V is the step of treating a disorder of the eye by administering outside the blood-retinal barrier a dsRNA complementary to a target gene in the eye. However, this cannot be the special technical feature because the process is taught by the prior art, as explained in the previous Action mailed 5/16/07. See the rejection now pending under 35 USC 102 over King et al. (US 2002/0165158 A1). King et al. taught methods for making and using siRNA targeted to PKC $\beta$  to treat angiogenesis-related disorders, including diabetic retinopathy and other neovascular disorders of the eye (page 1, 8, 10, and 11, for example). It is taught that the agent [the PKC $\beta$  antagonist] may be administered to the eye, e.g., as aqueous eye drops or in a cream, lotion or other vehicle suitable for administration onto the eye surface (paragraph 125, page 10), systemically, or transmucosally (paragraph 190). Accordingly, unity of invention among Groups I-V is lacking *a posteriori*.

Therefore, Groups I-V are drawn to different methods that do not share the same or corresponding technical feature.

The special technical feature of Group I is, therefore, considered to be the preparation of dsRNA for administration outside the blood-retina barrier to treat an eye disorder, which is not present in or specifically required by any other group. The special technical features of Group II and III are diagnosing a subject with 1) a disorder or 2) a predisposition to a disorder of the eye, followed, preceded by, or done concurrently with the administration of dsRNA outside the blood-retina barrier to treat an eye disorder, which processes are not present in or specifically required by any other group. Similarly, the special technical features of Groups IV and V are administration of dsRNA outside the blood-retina barrier to treat an eye disorder followed, preceded by, or done concurrently with 1) detection of a product of the target gene or 2) isolation of said target gene, which processes are not present in or specifically required by any other group. Accordingly, unity of invention is lacking *a priori*.

#### ***Linked Inventions***

Claim 1 link(s) inventions I-V. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Conclusion***

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LW  
Examiner, AU1635  
March 30, 2008

/Sean R McGarry/  
Primary Examiner, Art Unit 1635